JAN 1 8 2002

K013494

510(K) SUMMARY

Pursuant to 510(i) of the Federal Food, Drug, and Cosmetic Act, as Amended.

Company Name:	Sulzer Dental Inc.
Address:	1900 Aston Avenue, Carlsbad, CA 92008-7308
Telephone Number:	760-929-4104
Registration Number:	2023141
Contact Person:	Foster Boop
Date Summary Prepared:	January 16, 2002
Classification Name:	Implant, Endosseous (76DZE)
Common/Usual Name:	Dental Implant
Device Trade Name:	Spline Twist

The primary devices used for comparison in this summary are the dental implants and indications for use clear under the Branemark System (K992937 and K993595) and the ITI implants (K984104 and K002374).

1. **Intended Use:**

Sulzer Dental's implant systems are designed for use in edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a freestanding single tooth replacement. The use of the 5.0mm implant is recommended when the quantity and density of bone would dictate the use of an implant larger than 4.0mm. In patients with an edentulous mandible, Spline Twist implants may be loaded immediately when at least four implants are placed between the mental foramina and rigidly splinted with a bar.

a) **Description:**

Spline Twist implants are screw type implants made from titanium alloy. They have the same surfaces as currently available Sulzer Dental implants. The implants are all provided sterile.

b) **Technological Characteristics:**

There have been no modifications to the Spline Twist implants. There has been no change to the implant materials or to the implant/abutment interface.

c) **Comparison Analysis:**

The overall design of the Spline Twist implants are similar to the predicate implants. See **Table 1** below for a comparison of the Advent and Swiss Plus implants and the predicate devices.

Table 1: Summary of Comparison

Characteristic	Branemark System	ITI Implants	Spline Twist
Intended Use	Intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patients chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.	Intended for surgical placement in the maxillary and/or mandibular arches to provide support for prosthetic restorations in edentulous or partially edentulous patients.	Intended for surgical implantation in edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a freestanding single tooth replacement.
Indication	Immediate Load	Immediate Load	Immediate Load
Design	Threaded, root form implant	Threaded, root form implant	Threaded, root form implant
Placement Method	Two or Single Stage Surgery	Single Stage Surgery	Two or Single Stage Surgery
Material	Commercially Pure Titanium	Commercially Pure Titanium	Titanium alloy
Diameter (mm)	3.75mm and 4.0mm	3.3mm, 4.1mm and 4.8mm	3.75mm & 5.0mm
Lengths	10mm – 18mm	8mm – 16mm	8mm – 18mm*
Implant Surface	Machined Roughened – TiUnite	TPS coated Roughened – Sandblasted Largegrit Acid washed (SLA)	HA coated or Roughened – HA blasted
Packaging	Glass ampoule in peel-open blister pack	Ampoule	Vial inside rigid PETG tray
Sterilization	Dry heat	Gamma irradiation	Gamma irradiation

* The use of implants with length less than 10mm are not recommended for immediate load use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 8 2002

Mr. Foster Boop
Manager, Submissions & Complaints
Sulzer Dental, Incorporated
1900 Aston Avenue
Carlsbad, California 92008-7308

Re: K013494
Trade/Device Name: 3.75MM and 5.0MM Spline Twist Implant
Regulation Number: 872.3640
Regulation Name: Dental Implant or Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: October 19, 2001
Received: October 22, 2001

Dear Mr. Boop:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K013494

Device Name: 3.75mm & 5.0mm Spline Twist

Indications for Use:

The Spline Twist implants are intended for surgical implantation in edentulous or partially edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a freestanding single tooth replacement. The use of the 5.0mm implant is recommended when the quantity and density of bone would dictate the use of an implant larger than 4.0mm. In patients with an edentulous mandible, Spline Twist implants may be loaded immediately when at least four implants are placed between the mental foramina and rigidly splinted with a bar.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013494